

B1
1. (twice amended) A method for inhibiting cancer cell growth or killing cancer cells comprising eliciting an antigen specific immune response with an immunologically effective amount of a composition comprising a [lipid or lipid] phosphatidylserine /polypeptide conjugate.

B2
7. (amended) The method of claim 1, wherein said immune response is elicited with [lipid] phosphatidylserine/polypeptide conjugate comprising a polypeptide selected from the group consisting of BSA, KLH, BGG, diphtheria toxin, and β 2-glycoprotein I.

B3
12. (amended) A method of generating an antigen specific immune response, comprising administering to an animal a pharmaceutical composition comprising an immunologically effective amount of a [phosphatidylcholine/polypeptide or a] phosphatidylserine/polypeptide conjugate composition.

B4 17 ~~30~~ 29. (amended) The method of claim [40] ~~31~~ ¹⁶, wherein said human has a tumor. *Cancer is comprised within a tumor*

B5
43. (amended) The method of claim 12, wherein said immune response is elicited with a [lipid or lipid] phosphatidylserine/polypeptide conjugate comprising a polypeptide selected from the group consisting of BSA, KLH, BGG, diphtheria toxin, and β 2-glycoprotein I.

B6 22 44. (amended) The method of claim [44] ~~45~~ ²¹, wherein said polypeptide is β 2-glycoprotein I.

II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-8, 11, 12, and 28-44 were pending at the time of the present action. Claims 11 and 28 have been canceled. Claims 1, 7, 12, 39, 43 and 44 have been amended. Support for the amendments may be found throughout the specification, for example at page 4 lines 10-14. Claims 1-8, 12, and 29-44 are currently pending. The pending claims are reproduced in Appendix A for the Examiner's convenience.

B. The Rejections under 35 U.S.C. § 112, Second Paragraph, are Overcome

The Action rejects claims 11 and 39 under 35 U.S.C. §112, first paragraph as being indefinite. The Action asserts that claims 11 and 39 contain terms that lack antecedent basis or are unclear. Applicant respectfully traverses.

The legal standard for definiteness is whether a claim, read in light of the specification, reasonably apprises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed.Cir. 1991). Applicant has amended claim 39 to overcome the issues noted by the Action. Claim 11 has been canceled. Applicant submits that the claims, as amended, when read in light of the text of the specification satisfy the definiteness requirement of §112, second paragraph. Applicant therefore respectfully requests that these rejections be removed.

C. The Rejections under 35 U.S.C. § 112, First Paragraph, are Overcome

The Action rejects claims 1-8, 11-12 and 28-44 under 35 U.S.C. §112, first paragraph. The Action argues that the specification does not enable any person skilled in the art to practice the invention commensurate in scope with the claims. Specifically, the Action asserts that the claims are drawn to eliciting an immune response directed against a lipid alone. The Action further asserts that claims drawn to a lipid/polypeptide conjugate are also overly broad. Applicant respectfully traverses.

Applicant has amended the claims to more specifically point out and distinctly claim the subject matter applicant regards as the invention. As the Action acknowledges, the specification is enabling for “a method of generating an immune response, inhibiting cancer growth or killing cancer cells with an immunologically effective amount of a phosphatidylserine/polypeptide

conjugate composition. Applicant has amended the claim to reflect that the lipid polypeptide conjugate is a phosphatidylserine/polypeptide conjugate. While Applicant does not concede that the Action's arguments are well-founded, the claims have been amended in the interest of expediting prosecution and placing the instant application in condition for allowance. Applicant therefore respectfully requests that this rejection be removed.

D. The Rejections under 35 U.S.C. § 102 over Creaven *et al.* are Overcome

The Action rejects claim 1-6, 11-12 and 28-42 under 35 U.S.C. §102(b) as being anticipated by Creaven *et al.* The Action asserts that Creaven *et al.* teaches a method for inhibiting cancer cell growth or killing cancer cells with an immunologically effective amount of a composition comprising a lipid or lipid/polypeptide conjugate, wherein the cancer cell is a renal cancer cell. Applicant respectfully traverses the maintenance of this rejection.

In order to support a rejection under §102, the cited prior art reference must contain each limitation of the allegedly anticipated claim and enable one skilled in the art to make the subject matter. *Chester v. Miller*, 906 F.2d 1574, 1576 n. 2, 15 U.S.P.Q.2d 1333, 1336 n. 2 (Fed.Cir. 1990). While Creaven *et al.* may teach the elicitation of an immunological response with a composition that includes a lipid/polypeptide conjugate, the response mediated by the administration of the composition as taught by Creaven *et al.* is a non-specific macrophage mediated response. Claims 1 and 12, as currently pending, are directed towards the elicitation of an antigen specific response, *i.e.* a humoral or cellular response. A person of ordinary skill would recognize that the ability to activate macrophages would not equate to the ability to initiate the immunological cascade necessary to facilitate the development of an antigen specific humoral or cellular response.

Further, the MTP-PE as taught by Creaven *et al.* is the immunostimulatory component of the composition taught by the reference. The lipid of the composition is used to embed the compound in the liposome and is of little relevance in the induction of the immune response.

Thus, Creaven *et al.* does not contain every limitation of the allegedly anticipated claims and is insufficient to enable one skilled in the art to make the subject matter. Creaven *et al.* is therefore insufficient to maintain the instant rejection. Applicant therefore respectfully requests that this rejection be removed.

E. The Rejections under 35 U.S.C. § 102 over Fidler, *et al.* are Overcome

The Action rejects claim 1, 5-6, 11 and 28 under 35 U.S.C. §102(b) as being anticipated by Fidler *et al.* The Action asserts that Fidler *et al.* teaches a method for inhibiting cancer cell growth or killing cancer cells comprising eliciting an immune response with an immunologically effective amount of a composition comprising a lipid or lipid/polypeptide conjugate. Applicant respectfully traverses the maintenance of this rejection.

In order to support a rejection under §102, the cited prior art reference must contain each limitation of the allegedly anticipated claim and enable one skilled in the art to make the subject matter. *Chester v. Miller*, 906 F.2d 1574, 1576 n. 2, 15 U.S.P.Q.2d 1333, 1336 n. 2 (Fed.Cir. 1990). Fidler *et al.* relates to a pharmaceutical administration systems when applied in the form of liposomes to stimulate macrophage activity for use in cancer therapy. As argued above, Claims 1 and 12, as currently pending are directed towards the elicitation of an antigen specific response, *i.e.* a humoral or cellular response. A person of ordinary skill would recognize that the ability to activate macrophages would not equate to the ability to initiate the immunological cascade necessary to facilitate the development of an antigen specific humoral or cellular

response. Thus, Fidler, *et al.* does not contain every limitation of the allegedly anticipated claims and is insufficient to enable one skilled in the art to make the subject matter. Fidler *et al.* is therefore insufficient to maintain the instant rejection. Applicant therefore respectfully requests that this rejection be removed.

F. The Rejections under 35 U.S.C. § 103 over Creaven, *et al.* in view of Gupta *et al.* are Overcome

The Action rejects claim 1-7, 11-12 and 28-43 under 35 U.S.C. §103 as being obvious over Creaven, *et al.* in view of Gupta *et al.* are overcome. The Action asserts that Creaven *et al.* teaches a method for inhibiting cancer cell growth or killing cancer cells with an immunologically effective amount of a composition comprising a lipid or lipid/polypeptide conjugate, wherein the cancer cell is a renal cancer cell. The Action asserts that Gupta *et al.* teaches that the use of a carrier protein facilitates the elicitation of a higher immunogenic response. Applicant respectfully traverses the maintenance of this rejection.

The consistent criterion for the determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that a claimed process should be carried out and would have a reasonable likelihood of success viewed in the light of the prior art. *University of California v. Synbiotics Corp.*, 29 U.S.P.Q.2d 1955, 1956 (Cal. 1993). Thus, in order to support an obviousness rejection, all the claim limitations must be taught or suggested by the references. MPEP §2143.03. As argued above, Creaven *et al.* may teach the elicitation of an immunological response with a lipid/polypeptide conjugate, the response mediated by the administration of a lipid polypeptide as taught by Creaven *et al.* is, however, a non-specific macrophage mediated response. A person of ordinary skill would recognize that the ability to activate macrophages as taught by Creaven *et al.* would not equate to the ability to initiate the